***In re National Prescription Opiate Litigation*: MDL 2804**
Summary Sheet of Concise Issues Raised

Opposition Name: Plaintiffs' Memorandum in Opposition to Defendant Rite Aid of Maryland's Motion for Summary Judgment

Opposing Parties: Plaintiffs Summit County and Cuyahoga County

Concise Description: Rite Aid of Maryland ("Rite Aid") moved for Summary Judgment on all claims, arguing that Plaintiffs failed to offer any evidence that Rite Aid failed to maintain effective controls against diversion. In particular, Rite Aid argues that a purported lack of expert evidence dooms Plaintiffs' case against Rite Aid. Rite Aid's argument fails because there is ample undisputed evidence -- much of it Rite Aid's own admissions -- that Rite Aid did not maintain effective controls against diversion and had no system to identify and report suspicious orders. ***Indeed, Rite Aid never identified or reported a single suspicious order.***

Expert testimony is not needed when, as here, the breach of duty is so obvious as to be easily recognized by the average juror. Rite Aid admits that it *never* identified *any* suspicious orders before shipment. Rite Aid never reported any suspicious orders to DEA. Notwithstanding the obvious violations that flow from Rite Aid's having failed to identify or report a single suspicious order, the undisputed facts show that Rite Aid had suspicious orders from numerous sources. Rite Aid serviced customers from "pill mill" doctors who were indicted. Rite Aid's pharmacists lost their licenses for stealing opioids. Rite Aid entered into a settlement with the United States which included a finding that "Rite Aid knowingly filled prescriptions for controlled substances that were not issued for a legitimate medical purpose." Rite Aid maintained a list of "suspicious prescribers."

The above aside, even if expert testimony is required to prove Plaintiffs claims, Plaintiffs have offered it. Plaintiffs designated Dr. Whitelaw as an expert on the relevant standards surrounding the design, implementation, and operation of corporate and controlled substances compliance programs for the pharmaceutical industry.

Moreover, the undisputed factual record shows Rite Aid violated the CSA in nearly all the same ways the defendant did in *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017). Rite Aid only identified suspicious orders after shipment; Rite Aid used a threshold-based suspicious order monitoring system; Rite Aid cut above-threshold orders to below threshold before shipment without performing the requisite due diligence; and Rite Aid did not maintain detailed records of past orders.

Lastly, the government audits that Rite Aid argues are evidence of its effective controls against diversion are both inadmissible and do not evidence Rite Aid's compliance with the CSA requirements. The DEA expressly stated that Rite Aid's 2005 and 2012 audits were "not designed to endorse suspicious order monitoring systems."

Filing Date: June 28, 2019 (Dkt. 1779)
Response Date: July 31, 2019
Reply Date: August 16, 2019

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL 2804
	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track One Cases	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT RITE AID OF MARYLAND'S MOTION FOR SUMMARY JUDGMENT

July 31, 2019

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INTRODUCTION

Rite Aid of Maryland ("Rite Aid") erroneously contends that because Plaintiffs have offered no proof at all Rite Aid violated the Controlled Substances Act (CSA), 21 U.S.C. §§ 801 *et seq.*, and Rite Aid allegedly has *some* evidence of compliance, Rite Aid is entitled to dismissal of all of Plaintiffs' claims. The reality, however, is that the Plaintiffs have presented overwhelming undisputed evidence that Rite Aid violated the CSA by not maintaining effective controls against diversion, specifically by failing to identify and report suspicious orders. Likewise, the undisputed evidence shows that Rite Aid's failure to maintain effective controls against diversion led to the damages and injuries of Plaintiffs. The court should ignore Rite Aid's *ipse dixit* arguments and deny its Motion.

ARGUMENT

I. LEGAL STANDARD

The moving party has the burden of showing that no genuine dispute exists as to any material fact. *Hickle v. Am. Multi-Cinema, Inc.*, 927 F.3d 945, 951 (6th Cir. 2019). Summary judgment must be denied "if a reasonable jury could return a verdict for the nonmoving party[.]" *Kolesar v. Allstate Ins. Co.*, No. 1:19 CV 35, 2019 WL 2996047, at *2 (N.D. Ohio July 9, 2019) (Polster, J.) (citing *Baynes v. Cleland*, 799 F.3d 600, 606 (6th Cir. 2015)). In making this determination, "the court must view the facts and any inferences reasonably drawn from them in the light most favorable to the nonmoving party." *Id.* (citing same). Courts do not weigh the evidence or otherwise engage in "jury functions" in deciding a motion for summary judgment; "[i]f there remains any material factual disagreement as to a particular legal claim, that claim must be submitted to a jury." *Hickle*, 927 F.3d at 951 (citing *Bobo v. United Parcel Serv., Inc.*, 665 F.3d 741, 748 (6th Cir. 2012)).

II. AMPLE UNDISPUTED EVIDENCE SHOWS RITE AID'S FAILURE TO MAINTAIN EFFECTIVE CONTROLS AGAINST DIVERSION

Rite Aid argues it is entitled to summary judgment because Plaintiffs have completely failed to offer any evidence that Rite Aid failed to maintain effective controls against diversion. In particular,

Rite Aid argues that a purported lack of expert evidence dooms Plaintiffs' case against Rite Aid. But there is ample undisputed evidence - much of it Rite Aid's own admissions - that Rite Aid did not maintain effective controls against diversion and had no system to identify and report suspicious orders.[1]

A. Expert Testimony Is Not Required to Establish Rite Aid's Liability Given Rite Aid's Admissions and the Undisputed Facts

Rite Aid is incorrect that expert testimony is required for Plaintiffs to prove their case; expert testimony is not needed when the breach of duty is so obvious as to be easily recognized by the average juror. Under federal and Ohio law, "it is the accepted rule that expert testimony is not necessary for the proof of negligence in non-technical matters or those of which an ordinary person may be expected to have knowledge, or where the lack of skill or want of care is so obvious as to render expert testimony unnecessary." *Evangelista v. Black*, 126 N.E.2d 71, 75 (Ohio. App. 1953).[2] The common knowledge exception has been applied in numerous instances under federal law and Ohio law. *See e.g. United States v. Elliot*, 876 F.3d 855, 866 (6th Cir. 2017) (finding in a conspiracy to distribute oxycodone case that expert testimony was not necessary where there is "evidence of plainly improper prescribing practices that a lay juror could recognize as illegitimate"); *Howell v. Miller*, 5:16-CV-1623, 2017 WL 3698617, *2 (N.D. Ohio Aug. 28, 2017) ("the fact that sleepwalking may result in injury is common

[1] The evidence that Rite Aid violated the CSA and implementing regulations is so clear that Plaintiffs moved for summary judgment as to Rite Aid on the issue. *See* Memorandum of Law in Support of Plaintiffs' Motion for Partial Summary Adjudication that Defendants Did Not Comply with Their Duties under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them (Dkt # 1924-1) ("CSA-Compliance Brief").

[2] The case law relied on by Rite Aid for the proposition that expert testimony is required to prove that the defendant maintained an ineffective suspicious order monitoring system is clearly distinguishable and not relevant to the question before this Court. *Ramage v. Cent. Ohio Emergency Serv., Inc.*, 592 N.E.2d 828, 833 (Ohio 1992) (requiring proof of the recognized standard of care in a medical malpractice claim); and *Thompson v. Bingham Greenebaum Doll LLP,* ___ N.E. 3d__, 2019 WL 2308045 (Ohio App. May 24, 2019) (requiring expert testimony as to the professional standards of performance in a legal malpractice action). In addition, both cases recognize the "common knowledge" exception which provides that, "matters of common knowledge and experience, subjects which are within the ordinary, common and general knowledge and experience of mankind, need not be established by expert testimony." *Ramage*, 592 N.E.2d at 833 (citing *Johnson v. Grant Hosp.* (1972), 31 Ohio App.2d 118, 124-125, 286 N.E.2d 308, *rev'd on other grounds* (1972), 32 Ohio St.2d 169, 291 N.E.2d 440; *Thompson*, 2019 WL 2308045 at *5.

knowledge easily understood by a lay juror); *Ackley v. Secretary of Health and Human Services*, 925 F.2d 1462, *2 (6th Cir. 1991) (the existence of uncomplicated and non-stressful jobs is a fact that is "within the common knowledge and experience of ordinary men, and requires no substantiation by a vocational expert"); *Kennedy v. City of Zanesville, Ohio,* No. 2:03-CV-1047, 2008 WL 2036713, at *1 (S.D. Ohio 2008) (expert testimony is not needed regarding indirect injuries suffered from not having potable water which fall within the boundaries of common knowledge). Beyond the federal courts, the Federal Government has recognized that "even to a layman" orders of unusual size can be suspicious, as can orders that deviate from a normal pattern by over 100%. Denial of Application for Registration, Morton Pharm., Inc. 38 Fed. Reg. 9,526 (April 17, 1973).

Here, common knowledge alone is all that is needed to understand Rite Aid's CSA violations. Rite Aid admits that it *never* identified *any* suspicious orders before shipment, much less reported any suspicious orders to DEA. *See* Exh. 1 (Response to Plaintiffs' First Set of Combined Discovery Requests to National Retail Pharmacy Defendants at Nos. 3 and 4).[3] No expert testimony is needed to draw the logical conclusion that Rite Aid did not maintain effective controls against diversion because Rite Aid never identified or reported *a single* suspicious order during the height of the opioid epidemic.

Furthermore, no expert is needed to opine on the fact that Rite Aid did not report orders that Rite Aid could have readily identified as suspicious, a clear violation of the CSA. The undisputed evidence shows that Rite Aid maintained a list of what it called "suspicious prescribers," but it failed to ever identify or report any of the suspicious prescribers' orders as suspicious. Janet Hart Dep. (1/31/19), Dkt. # 1962-22 at 163:4-10; *id.* at 173:1-22. Similarly, the evidence shows that Rite Aid

[3] The criminal information for distributor Rochester Drug Cooperative (RDC) for violations of the CSA specifically notes as evidence of failure to comply with the CSA the fact that from 2012-2017 RDC only reported 4 suspicious orders total. *See* Exh. 2 at ¶ 39. Rite Aid reported zero.

identified "suspicious orders" through its Asset Protection systems, but it only did so after shipment and in any event, Rite Aid never reported them to DEA. *Id.* at 269:10-22.

Beyond the orders Rite Aid itself admits came from suspicious prescribers or were identified as suspicious after shipment, other examples of the failure to identify suspicious orders abound in the undisputed record. Rite Aid did not identify or report, as suspicious, orders from stores dispensing opioids to customers of a notorious, convicted Ohio pill-mill doctor. *Id.* at 186:3-8; Exh. 3 (MCKMDL00632923–0632925). Rite Aid also failed to identify any suspicious orders from stores where its pharmacists lost their licenses for diverting controlled substances. Hart Dep. (1/31/19), Dkt. #1962-2 at 210:13-18 (never reported any suspicious orders from stores where pharmacist Marcus Kins was stealing controlled substances); *id.* at 217:15-23 (never reported any suspicious orders from stores where pharmacist Henry Kozik was stealing controlled substances). Moreover, when the DEA found that "Rite Aid knowingly filled prescriptions for controlled substances that were not issued for a legitimate medical purpose"[4] Rite Aid never identified any suspicious orders as a result. *Id.* at 196:15-20.[5]

In the face of the evidence, Rite Aid's having offered an expert in support of its suspicious order monitoring (SOM) efforts does not warrant summary judgment in Rite Aid's favor. No specialized or technical knowledge is needed to conclude that a system that never identifies a suspicious order is no system at all. To argue otherwise flies in the face of Rite Aid's own admission of the existence of suspicious prescribers, the undisputed evidence that suspicious orders existed in

[4] Rite Aid Corporation and Subsidiaries Agree to Pay $5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act, *available at* https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations.

[5] In Ohio more recently, Rite Aid stores were raided for the very same reason: dispensing prescriptions that were not for legitimate medical purposes. *See* https://fox8.com/2019/06/04/federal-agents-execute-search-warrants-at-several-rite-aid-pharmacies/

Rite Aid's distribution chain, numerous concrete examples of other suspicious orders, and common knowledge.

B. Plaintiffs Offered Expert Testimony, Although It Is Not Required

Even if expert testimony were required to prove Plaintiffs claims, Plaintiffs have offered it. As the Advisory Committee Notes regarding Fed. R. Evid. 702 explicitly acknowledge: "[R]ule [702] accordingly recognizes that an expert on the stand may give a dissertation or exposition of scientific or other principles relevant to the case, leaving the trier of fact to apply them to the facts." Fed. R. Evid. 702, Advisory Committee Notes – 1972 Proposed Rules.

Here, Plaintiffs designated Dr. Seth Whitelaw as an expert on the relevant standards surrounding the design, implementation, and operation of corporate and controlled substances compliance programs for the pharmaceutical industry. *See* Report of Seth Whitelaw, J.D., L.L.M., Dkt. # 2000-26 at 2. Contrary to Rite Aid's contention, Dr. Whitelaw's opinions were not limited to merely the analysis of compliance controls by other distributors. Rather, Dr. Whitelaw set forth the standard of care for the pharmaceutical *industry*, which included Rite Aid as a distributor, in regard to SOM policies.

Dr. Whitelaw opined that a review of the DEA regulations and general guidance letters provided to all registrants provided a clear concept of what a successful SOM program should look like and provided a summarized list of SOM requirements derived from those sources, which included at the most fundamental level, *inter alia*, "there must be a designed system" and "it must be operational." *Id.* at 33. Additionally, the system must identify suspicious orders of controlled substances, which must be reported as soon as they are discovered, and which must not be filled unless and until it can be ascertained that the order will not be diverted. *Id.* Dr. Whitelaw also set forth in detail the attributes for a robust distributor anti-diversion program, *id.* at 34-36, certain of which were specifically noted to relate to "large retail pharmacy chains (e.g. CVS, Walgreens, and Rite Aid)."

Plaintiffs provided evidence showing that Rite Aid developed, but never implemented, a suspicious order monitoring system (*i.e.*, the system was never operational). Additionally, evidence shows that Rite Aid's distribution system made it impossible to identify and report suspicious orders, and in fact, Rite Aid never identified or reported a suspicious order, despite the fact that it had suspicious orders from "pill mill" doctors, suspicious orders evidenced in a DEA settlement, and suspicious orders from Rite Aid's own list of "suspicious prescribers," among other things. Plaintiffs' experts such as Dr. Whitelaw satisfy any need for expert testimony by establishing the standard of care needed even if they do not specifically opine on the ultimate question of Rite Aid's violations of that standard.

C. Undisputed Facts Show That Rite Aid Did Not Maintain Effective Controls Against Diversion As A Matter Of Law

DEA registrants are required to maintain effective controls against diversion, including operating a system to identify and report "suspicious orders." In *Masters Pharm., Inc. v. Drug Enf't Admin.,* 861 F.3d 206 (D.C. Cir. 2017), the court held that shipping a suspicious order first, without conducting due diligence, and then reporting the order as suspicious to DEA after shipping, was a violation of the CSA. *See Masters*, 861 F.3d at 212–13. Furthermore, *Masters* established the legal standard for a distributor using a threshold-based system to identify and report suspicious orders in order to be compliant with the CSA.[6]

Masters establishes that it is "the attempt to obtain unusual amounts of controlled substances" that makes an order suspicious, not what is ultimately shipped. *Masters*, 861 F.3d at 217–18. Thus, editing or "cutting" orders to below the threshold and then shipping that amount is a violation of the

[6] The DEA has stated that "Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders." Exh. 4 (Rannazzisi DEA Registrant Letter dated Dec. 27, 2007). Rite Aid's threshold was set at a rigid 5,000 dosage units, per store, per order. This too was a violation of the CSA and its implementing regulations.

CSA. *Id.*[7] Additionally, *Masters* holds that to be complaint with the CSA, the registrant must perform due diligence on orders that exceed the threshold to confirm the order is not suspicious before shipment. *See Masters,* 861 F.3d at 217. To satisfactorily perform the requisite due diligence, a distributor, such as Rite Aid, must maintain detailed records of past orders. *Masters*, 861 F.3d at 217 (the "limited investigative records" distributor maintained prevented compliance with the required due diligence). *Masters* made its findings on a robust factual record and without expert testimony.

Similarly, the undisputed factual record in this case shows Rite Aid violated the CSA in nearly all the same ways the defendant did in *Masters*. Rite Aid admits that the only suspicious orders it identified were only identified as suspicious after shipment. Hart Dep., # 1962-22 at 173:1-22 (when an order is identified as suspicious through Asset Protection, "the order has already been shipped to the store"). Rite Aid also used a threshold-based suspicious order monitoring system. *Id.* at 235:6-19. With respect to the threshold-based system, the undisputed facts also show that Rite Aid cut above-threshold orders to below threshold before shipment, *id.* at 251:23-252:4, but Rite Aid did not perform the requisite due diligence on above-threshold orders, Debra Chase Dep. (1/4/19), Dkt. # 1959-21 at 94:7-18; Marian Wood Dep. (1/24/19), Dkt. # 1972-10 at 144:8-13, nor did it maintain detailed records of past orders. Exh. 5 (Rite_Aid_OMDL_0014035–0014036). These facts are undisputed and they constitute violations of the CSA according to the legal standards articulated in *Masters*. The violations as matter of law are sufficient to deny Rite Aid's motion for summary judgment.

D. Government Audits Do Not Support Rite Aid's Motion

The government audits that Rite Aid argues are evidence of its effective controls against diversion are both inadmissible and do not evidence Rite Aid's compliance with the CSA requirements. "It is well established that a court may not consider hearsay when deciding a summary judgment

[7] The criminal information for distributor Rochester Drug Cooperative (RDC) specifically notes that RDC was in violating the CSA by cutting orders. *See* Exh. 2 at ¶ 33.

motion." *Tranter v. Orick*, 460 F. App'x 513, 514 (6th Cir. 2012). Evidence which is irrelevant to the issue presented must also be disregarded when deciding a summary judgment motion. *U.S. Structures, Inc. v. J.P. Structures, Inc.*, 130 F.3d 1185, 1189 (6th Cir. 1997).

Here, the DEA audits cannot provide support for Rite Aid's Motion for Summary Judgment because the evidence about those audits on which Rite Aid heavily relies is inadmissible hearsay. Rite Aid contends that DEA concluded from the 2012 audit that Rite Aid had an "excellent excessive order monitoring program." Dkt. 1779 at 3. Rather, what DEA may have said to unidentified Rite Aid employees or concluded only appears in a self-serving Rite Aid-transcribed summary about the 2012 audit.[8] In deposition, the author of that summary could not even identify the Rite Aid employee who was allegedly told this by DEA, and there was no record of which Rite Aid employees were working on the day in question. Exh. 6 (Keith Frost Dep. (1/15/19) at 314:18-315:11). Similarly, the evidence of a "flawless" 2005 DEA audit only comes from a self-serving summary transcribed by a Rite Aid about what DEA supposedly said.

Underscoring the fact that such documents are unreliable and inadmissible, DEA itself directly contradicts Rite Aid's characterization of the DEA audits. Specifically, in an apparent recognition of the hearsay issue, Rite Aid sought the testimony of one of the DEA investigators who conducted the 2012 Audit. In opposing that request, the DEA stated that the 2005 and 2012 audits were "not designed to endorse suspicious order monitoring systems." Exh. 7 (DEA Affidavit at ¶ 10). Furthermore, in its letter brief responding to Rite Aid's motion to compel, DEA stated that "the DEA's investigations focused on the site's physical security and record-keeping and simply do not speak to the design or functionality of Rite Aid's suspicious order monitoring system." Exh. 7 (DEA Letter Brief at 3). DEA continued: "As DOJ conveyed to Rite Aid's counsel, and consistent with Rite

[8] Even if admissible, Rite Aid cannot be allowed to cherry-pick the DEA statements to rely on. DEA has fined Rite Aid, and issued guidance that belies its arguments here. *See e.g.* Exh. 4 (Rannazzisi DEA Registrant Letter dated Dec. 27, 2007).

Aid's own documents, the 2005 report does not contain even a single mention of a suspicious order monitoring system, and the two reports relating to the 2012 investigation contain only a passing mention by Rite Aid of such systems and only in the context of the closing discussion." *Id.* This fact can be plainly seen even in Rite Aid's description of the 2005 audit; nowhere in it does Rite Aid record any alleged DEA statements about its SOM system.

Likewise, the Rite Aid characterizations of what happened during Maryland state audits are inadmissible hearsay and, even if admissible, contain no information about the sufficiency of Rite Aid's suspicious order monitoring systems. Indeed, the only quote Rite Aid was able to pull from those audits has to do with records of receipts of controlled substances – not suspicious order monitoring.

The government audits Rite Aid claims are "uncontroverted evidence" that Rite Aid maintained effective controls against diversion do not support summary judgment for Rite Aid at all. Just because the distribution center may have passed an audit, that evidence – even if it were admissible – is irrelevant and does not bolster Rite Aid's motion for summary judgment because the audits simply had nothing to do with evaluating suspicious order monitoring systems.[9]

III. PLAINTIFFS ADEQUATELY PLEAD CAUSATION

Plaintiffs separately filed an Opposition to Distributor and Pharmacy Defendants' Motion for Summary Judgment on Causation. *See generally* Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Proof of Causation. In that opposition, Plaintiffs demonstrate that each Distributor and Pharmacy Defendant caused sharply increased harms and costs from both licit and illicit opioid use in the Plaintiff Counties through their failures to failure to identify,

[9] The DEA also makes the important point that "even if the DEA had endorsed Rite Aid's suspicious order monitoring system – which it did not – that fact would only answer the question whether Rite Aid could identify suspicious orders. It would not answer the question whether Rite Aid took the appropriate steps upon identifying suspicious orders, which is the question at the heart of the plaintiffs' claims." Exh. 7 (DEA Letter Brief at 4).

block, and report suspicious orders. In fact, even Rite Aid itself recognizes the causal connection between the failure to identify, block, and report suspicious orders and diversion's attendant harms. *See e.g.* Exh. 8 (Rite_Aid_Aid_OMDL_0029789-29954 at 29794-29801 (describing how a dental surgery patient becomes addicted to controlled substances and then turns to street drugs)); Hart Dep. (1/31/19), Dkt. # 1962-22 at 23:19-23 (Rite Aid 30(b)(6) designee acknowledging that one of purposes of preventing diversion is to protect the public health). Plaintiffs demonstrate this causal connection with both statistical analysis of aggregate evidence by prominent public health economists and more individuated proof that each Pharmacy Defendant's intentional and negligent conduct was expected to and did cause these extensive harms. Plaintiffs incorporate those arguments herein by reference.

Rite Aid also incorrectly focuses on its percentage of the pills distributed into Summit and Cuyahoga Counties. The more relevant measure is the millions of opioid MME doses distributed by Rite Aid into those jurisdictions. This amount is more than enough to qualify as a significant factor in causing the Plaintiffs' harms. Furthermore, there is no requirement that Plaintiffs either establish Defendants caused the entire harm or apportion damages between each Defendant's wrongful or innocent conduct, and other contributing factors. W. Page Keeton et al., *Prosser & Keeton on the Law of Torts* § 52, p. 345. Instead, those arguments are related to divisibility or apportionment of the total damages as to which the defendant bears the burden.[10]

CONCLUSION

For the foregoing reasons, this Court should deny Rite Aid's Motion for Summary Judgment given the undisputed evidence showing that Rite Aid violated its duties under the Controlled Substances Act and caused harm to the Plaintiffs.

[10] To the extent Rite Aid argues that Plaintiffs' claims are wholly or partially barred by the statute of limitations, Plaintiffs incorporate by reference their arguments contained in Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motion for Partial Summary Judgment on Statute of Limitations Grounds.

Dated: July 31, 2019

Respectfully submitted,

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